

WSA 2001 Proposed Project Plan

Project Name:	Total Exposure Study in US	#1148
Objective:	Measure the uptake of selected vapor phase and particulate smoke components for an appropriate U. S. population based on suitable biomarker(s).	
Deliverable(s):	Report and publication	
Need Addressed:	Providing a baseline for future cigarette-design related studies by 2002.	
Plan Area (select one):	Understanding S&H <input checked="" type="checkbox"/> Communication <input type="checkbox"/> Acceptance <input type="checkbox"/> Harm Reduction <input checked="" type="checkbox"/>	
Disease (select one):	Cancer <input type="checkbox"/> CVD <input type="checkbox"/> COPD <input type="checkbox"/> Repro <input type="checkbox"/> All <input type="checkbox"/> Other <input checked="" type="checkbox"/> (specify) benchmark of exposure	
Project Leader:	Roger Walk	

Tactics and Milestones:		Target Date:
For 2001		
Complete contracts with CRO for:		
• (1) Method development and repeatability testing, questionnaire development, data analysis plan	(1) December 22, 2000	
• (2) Pilot study	(2) January 31, 2001	
Establish:		
• (3) SRB	(3) February 16, 2001	
• (4) Consultants	(4) March 30, 2001	
Method development and repeatability testing, questionnaire and data analysis plan development		
• (5) Start	(5) January 8, 2001	
• (6) Complete	(6) May 31, 2001	
(7) Publication of study design	(7) July, 2001	
Pilot study		
• (8) Approved protocol	(8) July, 2001	
• (9) Complete Recruiting and Screening of volunteers	(9) September, 2001	
• (10) Complete Clinical Study Report	(10) December, 2001	
• (11) Complete Biomarker Report	(11) March, 2002	

CRITICAL RESOURCE ALLOCATION	
Internal Resources (WSA, INBIFO)	External Resources (other PMUSA, external vendors)

Robin Kinser (25%); T. Tricker (5%); B. Nelson (40%); G. Schepers (<5%); H.-J. Hausmann (<5%); K. Rustemeier (5%); W. Gomm (5%); R. Walk (30%); T. Sanders (<5%); W. Reininghaus (<5%); K. von Holt (5%); J. Oey (35%)

D. Leyden, R. Carchman, R. Rylander, J. Gear, C. Adams, D. Compton, D. Sica, C. Gennings, SRB, Contract Laboratory--\$1,350,000

2082464286